

Rejections under 35 USC §112, second paragraph

Claim 18 has been amended as suggested by the Examiner, obviating the rejection as it applies to “zag2.1, ZAP, tb1 and PCNA2.” Claim 18 has been further amended to specify maize kn1.

Claim 18 is also rejected as indefinite for reciting “enhanced vigor.” Applicants respectfully traverse the rejection, directing the Examiner’s attention to page 28 of the application, where “vigor” is defined. For the Examiner’s convenience, the definition is reproduced here:

“VIGOR of a plant, as used herein, refers to the relative health, productivity, and rate of growth of the plant and/or of certain plant parts, and may be reflected in various developmental attributes, including, but not limited to, concentration of chlorophyll, photosynthetic rate, total biomass, root biomass, grain quality, and/or grain yield. In *Zea mays* in particular, vigor may also be reflected in ear growth rate, ear size, and/or expansiveness of silk exertion. Vigor may be determined with reference to different genotypes under similar environmental conditions, or with reference to the same or different genotypes under different environmental conditions.”

The direction of change in each factor which reflects “enhanced” vigor would be readily recognized by one of skill in the art; thus Applicants submit that the term “enhanced vigor” is sufficiently defined.

Rejections under 35 USC §112, Written Description

Claims 18-19, 33-37, 44, 50-54 and 68-69 have been rejected for failing to meet the written description requirement.

The claims have been amended as suggested by the Examiner, in order to obviate the rejection.

Rejections under 35 USC §112, Enablement

Claims 18-19, 33-37, 44, 50-54 and 68-69 have been rejected for failing to meet the enablement requirement.

Applicants respectfully traverse the rejection.

The Examiner has noted the disclosed data and invited the Applicants to explain calculation of the data in the graphs of the application. Applicants thank the Examiner for the opportunity.

With regard to Figure 2, this graph shows Ear Growth Rate for nine events relative to the growth rate of nontransgenic control plants. Event 15846, for example, has a negative Ear Growth Rate *relative to* the rate for the nontransgenic controls. This is consistent with the claim language, “wherein said transgenic plant displays enhanced vigor *compared to a corresponding plant without said cassette*.” (emphasis added) Please see the text of Example 7 for more details of the experiment.

Similarly, Figure 3 shows performance of transgenics for several aspects of grain yield, relative to performance of nontransgenic controls. Please see the text of Example 8 for more details.

Figures 4, 5 and 6 are described in Example 9 (a well-watered trial).

Figures 7, 8, 9 and 10 are described in Example 10 (a drought stress trial).

The Examiner states that “Applicants have not stated a nexus between enhanced vigor and the phenotypic characteristics disclosed above.”

Applicants respond that the definition of vigor at page 28 of the application provides the nexus between the claims and the data shown in Figures 2-10. For example, Figure 2 shows ear growth rate; Figure 3 shows grain yield and ear size; Figures 4 and 7 show plant height; Figures 5, 6 and 9 show yield data; Figure 8 shows leaf greenness, i.e. concentration of chlorophyll; Figure 10 shows plant biomass. Each of these factors is specifically named in the application at page 28 in the definition of vigor, and the direction of change in each of these factors which reflects “enhanced” vigor would be readily recognized by one of skill in the art.

The Examiner states that Applicants have not exemplified the ZAP, tb1, PCNA2 and kn1 promoters or disclosed why these promoters can work in place of the maize zag2.1 promoter.

Applicants respectfully traverse; it has been established that “Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples.” *In re Wright*, 999 F.2d

1557, 27 USPQ2d 1510 (Fed. Cir. 1993) Applicants assert that the tissue-preferred expression pattern of the ZAP, tb1, PCNA2, and kn1 promoters is similar to that of zag2.1 and thus these promoters can be substituted in the construct. The ZAP promoter (SEQ ID NO: 5) was disclosed as an inflorescence-meristem-preferred promoter in 10/387,937 (published 2004/0025206) and in the child application 11/527,087, which specifically confirms the tissue-specificity of this promoter at Figure 6. The tb1 promoter (SEQ ID NO: 17) was disclosed as GenBank accession AF377742 in 2001, and the effect of tb1 on meristem activity was discussed in Hubbard, *et al.*, (2002) *Genetics* 162:1927-1935. The PCNA2 promoter (SEQ ID NO: 25) was disclosed in 10/388,359 (published 2005/0120404) as conferring cell-division and/or proliferation-specific expression preferential to the immature ear and early kernel tissue of maize. The kn1 promoter was disclosed in AY312169 as regulating the kn1 gene, which is expressed in shoot meristems; see, for example, Williams-Carrier, *et al.*, (1997) *Development* 124(19):3737-3745 (attached as Appendix A), and the Hake and Ori reference in the specification at page 44. Thus exemplification using the zag2.1 provides support for use of other promoters known to have similar expression patterns.

The Examiner states that IPT genes from Arabidopsis, Petunia and Agrobacterium are not equivalent and may produce different end products.

Applicants respond that the gene products of the Agrobacterium IPT gene and the plant IPT genes have the same function, i.e., to make active cytokinins. Agrobacterium and plant IPTs use different substrates (AMP and ADP or ATP respectively) but the end products (i.e., active cytokinins) are the same whether using a Arabidopsis, petunia or maize gene. For further support, please see Figure 1 in Hirose, *et al.*, (2008) *J. Exp. Botany* 59(1):75-83, attached as Appendix B.

The Examiner has found that undue trial and error experimentation would be required to practice the invention and that one of ordinary skill would need "to screen through the multitude of non-exemplified constructs".

In light of the amendments and arguments made herein, Applicants respectfully submit that the degree of experimentation is within reason and the full scope of the current claims should be granted. "The test [for undue experimentation] is not merely

quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention.” *Johns Hopkins University v. Cellpro, Inc.*, 152 F.3d 1342, 47 USPQ2d 1705 (Fed. Cir. 1998). (emphasis added) Applicants assert that a person of skill in the art, using conventional and well-known genetic engineering techniques, could apply the present teachings in a routine fashion to arrive at the claimed invention.

In view of the above amendments and remarks, Applicants respectfully submit that all grounds for rejection have been overcome and that the claims as amended are in condition for allowance.

Respectfully submitted,

/Karen K. Varley/

Karen K. Varley  
Agent for Applicant(s)  
Registration No. 45,751

PIONEER HI-BRED INTERNATIONAL, INC.  
Corporate Intellectual Property  
7250 N.W. 62<sup>nd</sup> Avenue  
P.O. Box 552  
Johnston, Iowa 50131-0552  
Phone: (515) 334-6780  
Facsimile: (515) 334-6883